REMARKS

This Amendment is respectfully submitted in response to the Office Action mailed May 22, 2009. It is timely submitted in view of the shortened statutory period for response of three (3) months set therein. Applicants request reconsideration in light of the following remarks.

Claim(s) 73-86 are pending in the application.

The Office Action of May 22, 2009 indicated that priority of the above-identified patent application should not be granted priority prior to the filing date of September 10, 2003. Applicants respectfully point out that there was ample basis in the Specifications of U.S. Patent Applications Serial Nos. 09/110,409 and 09/698,454 for the subject matter set forth in the above-captioned application. For example, the term "tretinoin" may be found in the original Specification of U.S. Serial No. 09/110,409 at p. 14, l. 23-26. U.S. Serial No. 09/110,409 repeatedly refers to the presence of proteins in the Specification, presupposing that such proteins are not denatured: for example, at p.15, l. 15-22 and p. 16, l. 1-3. In addition, Example 11 of U.S. Serial No. 09/110,409 at p. 31, l. 5-17 describe the preparation of soy materials containing soy trypsin inhibitor in which the soy is not exposed to heat or organic alcohols so as to preserve the nature of the proteins and not denature them.

Furthermore, U.S. Serial No. 09/698,454 refers to "non denatured soy product-containing compositions" at p. 1, l. 5. It refers to "non-denatured soymilk or powder" at p. 5, l. 3. Applicants therefore respectfully submit that the Office Action is in error with respect to failing to accord priority of the subject matter of the above-captioned patent application to its parent applications, U.S. Serial Nos. 09/110,409 and 09/698,454 and respectfully request reconsideration of the assignment of priority.

Applicants gratefully acknowledge the withdrawal of the rejection of Claims 73-86 under 35 U.S.C. 103(a) as being unpatentable over Meybeck et al., US 5,034,228 in view of Sessa et al. (1992) and Seiberg et al J. (1997).

The Office Action of May 22, 2009 rejected Claims 73-86 under 35 U.S.C. 103(a) as being unpatentable over Fowler et al (US 5,534,265) in view of Meybeck et al., US 5,034,228, Sessa et al. (1986), Seiberg et al. J. (1997) and Avramiotis et al (1996). The Office Action contended that the affidavit filed on March 11, 2009 (referred to in the Office Action as the "affidavit of KeShun Liu", (which was actually the Declaration of Miri Seiberg,

in which a work by KeShun Liu was cited) was "insufficient to overcome the Meybeck et al…reference." [Office Action, p. 3] The Office Action argues that "…Avramiotos et al. teach that soy lecithin's contains trypsin inhibiting acitivty (see entire abstract) and therefore, not all lecithins are denatured." [Office Action, p. 3]

The Office Action of May 22, 2009 further states that:

> Fowler teaches a non-abrasive personal cleanser comprising synthetic osy flour that may be combined with other anti-acne agents useful for cleaning the skin…However Fowler fails to teach the composition is for treating acne and also fails to teach the non-denatured soy extract and tretinoin as required by instant claim 73. Even though Fowler fails to specifically teach that the soy flour is non-denatured, Fowler teaches that "the water-insoluble micronized particles of the present invention can be derived from a wide variety of materials" including natural sources which reasonably would be non-denatured…Fowler also teaches retinoid as an anti-acne agent…Since Sessa teaches that soy flour comprises trypsin activity…one of ordinary skill in the art would have substituted Fowelr's synthetic soy flour with Sessa's natural flour and obtained non-denatured soybean extract.
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> Meybeck et al. teach treating acne with soya lecithin and tretinoin. It is known knowledge to one of ordinary skill in the art that soya lecithin is extracted from soybeans or soybean powder…However Meybeck fails to teach that the extracts are soy flour, soy paste and soymilk…One of ordinary skill in the art would have been motivated to combine Fowler with Meybeck and substitute the synthetic soy flour of Fowler and the soy lecithin in Meybeck with the soy flour os Sessa because Sessa teaches that soy flour comprises trypsin inhibiting activity. One of ordinary skill in the art would routinely add water to the soy flour and form a paste. Therefore the use of soy flour is equivalent to using soy paste as required by instant claims 74. Since tretinoin is known in the art to be interchangeable with retinoid or vitamin A, one of ordinary skill in the art would have employed either tretinoin or vitamin A in a composition for treating acne since vitamin A is well known in the art for treating acne…
>
> There is controversy to whether soy lecithin extract contains trypsin-inhibiting activity…Specifically Meybeck failed to teach whether soy lecithin is denatured or non-denatrued. It is known that defatted soy lecithin's are denatured. Meybeck is silent to that. Therefore it is reasonably expected that lecithin is non-denatured because it is derived from a natural source. Under such circumstances, where the product seems to be identical, then the burden shifts to applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention. [Office Action, pp. 4-6]

Applicant respectfully requests reconsideration of the foregoing rejection in light of the ensuing discussion.

Avramiotis et al. relates to microemulsions that contain lecithin and trypsin. First, applicants respectfully note that Avramiotis et al. relates to microemulsions into which lecithin and ***trypsin*** are placed. Avramiotis et al. does ***not*** refer to ***trypsin inhibitory*** proteins, rather, it relates specifically to a study of compositions containing ***trypsin***. Furthermore, nowhere does Avramiotis et al. imply or suggest that even the trypsin placed into the microemulsion was present in the soy-derived lecithin. Nor does Avramiotis et al. suggest or describe the presence of any soy trypsin inhibitory activity within the lecithin. Therefore, applicants respectfully contend that Avramiotis et al. is not at all relevant to the claims describing the compositions and methods of applicants' invention.

Fowler et al. does not remedy the deficiencies of Avramiotis et al. in leading one of ordinary skill in the art toward the compositions and methods of applicants' invention. Fowler et al. relates to "…nonabrasive thickened aqueous-based personal cleansing compositions. These compositions utilize insoluble micronized cleansing particles of defined particle size that are not tactilely perceived by the user during the cleansing process…" [Fowler et al., Abstract]. Applicants respectfully submit that the ***only*** mentions made of "soy" in Fowler et al. occur at col. 4, l. 38 in which Fowler et al. refers to "soy flour synthetic hectorite" to be used as a "water-insoluble, micronized particle…" [Fowler et al., col. 4, l. 18] The meaning of the term "soy flour synthetic hectorite" is unclear. "Hectorite" is a clay-type mineral.

Even if one were to assume that the phrase should be "soy flour, synthetic hectorite", indicating that the soy flour and synthetic hectorite are different materials, there is no description or disclosure or recognition that the soy flour should be non-denatured and include soy trypsin inhibitory activity. Moreover, Fowler et al. mentions in excess of ***sixty*** potential materials that could be used in the compositions set forth therein—there is no particular reason that one of ordinary skill in the art should have been directed to utilizing soy flour, much less non-denatured soy flour that contains soy trypsin inhibitory activity to arrive at the compositions and methods of applicants' invention.

The second reference to soy is at col. 13, l. 26-31, in which Fowler et al. describes derivatives of soybean oil as follows:

> Other anionic materials useful herein are soaps (i.e. alkali metal salts, e.g., sodium or potassium salts) of fatty acids, typically having from about 8 to about 24

> carbon atoms, preferably from about 10 to about 20 carbon atoms. The ***fatty acids used in making the soaps*** can be obtained from natural sources such as, for instance, plant or animal-derived glycerides (e.g., palm oil, coconut oil, soybean oil, castor oil, tallow, lard, etc.) The fatty acids can also be synthetically prepared. Soaps are described in more detail in U.S. Pat. No. 4,557,853, cited above. [Fowler et al., col. 13, l. 26-31] (emphasis added)

The derivation of such material from natural sources does not imply that the derived product necessarily contains non-denatured proteins. Fowler et al. merely indicates that a possible source for fatty acids, ***not proteins***, is soybean oil. One of ordinary skill in the art would not have been led to the compositions and methods of applicants' invention through a reading of Fowler et al., alone or in combination with Avramiotis et al. Proteins, being water-soluble, do not dissolve in oil, therefore, soybean oil is known not to contain proteins.

With regard to Meybeck, applicants respectfully point out that lecithin is an ***oil***—it is ***not*** a ***protein***. Oils cannot be denatured as can proteins. Thus, the appearance of lecithin in the compositions of Meybeck would not have taught one of ordinary skill in the art to formulate compositions containing active proteins such as soy trypsin inhibitor: Meybeck would have suggested the presence of lecithin, an oil that cannot be denatured.

Sessa et al. relates to the determination that trypsin inhibitor activity is present in toasted soybean flour. [Sessa et al., p. 784]. Sessa et al. does not remedy the inadequacies of Meybeck et al. in suggesting the compositions and/or methods of applicants' invention to one of ordinary skill in the art at the time of the invention. Nowhere does Sessa et al. indicate that trypsin inhibitor activity is useful in treating skin conditions. Rather, Sessa et al. merely indicates that there is trypsin inhibitor activity in soybean flour. In fact, Sessa et al. states that trypsin inhibitor activity may be related to negative physical effects in rats fed with toasted soybean flour and that ***its presence should be eliminated***:

> Since long term rat feeding studies with raw, toasted and overtoasted soybean flour treatments show a linear dose relationship for pancreatic lesion formation (1), our results are consistent with the hypothesis that attributes hyperplasia and tumor formation to the proteinaceous TI's [trypsin inhibitors]. ***Methods will be developed to inactivate the protease inhibitors, both in the purified state and in food systems.*** [Sessa et al., pp. 787-788] (emphasis added)

Thus, applicants respectfully submit that Sessa et al. would teach away from utilizing soybean extracts containing trypsin inhibitors.

Applicants respectfully submit that the Office Action is utilizing "hindsight" thinking in order to read into the cited art something that is not there and remains unrecognized therein. Nevertheless, the Office Action contends, without providing ***any*** supporting evidence or documentation from the cited art, that the methods of applicants' invention would have been obvious in view of the cited patents and publications. Applicants respectfully submit that this type of conjecture is tantamount to arriving at the claimed invention via hindsight. Applicants note that "...the obviousness inquiry cannot be performed using hindsight." *Orthopedic Equipt. Co., Inc.* v. *United States*, 702 F.2d 1055, 1012 (Fed. Cir. 1983). Applicants respectfully submit that the Office Action relies upon hindsight reasoning in justifying an obviousness rejection in spite of the fact that the cited publications and patents ***completely fail*** to suggest or describe the methods of applicants' invention.

In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of May 22, 2009. If there are any questions regarding this paper, the Examiner is respectfully invited to contact the undersigned. An early allowance is earnestly solicited.

Respectfully submitted,

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